(for example, experimental procedures) that are excluded from coverage under §405.310(k) of this chapter (medically unnecessary items and services), even though the beneficiary requires continued inpatient hospital care, if those services are furnished after the beneficiary (or the person acting on his or her behalf) has acknowledged in writing that the hospital (acting directly or through its utilization review committee and with the concurrence of the intermediary) has informed him or her as follows:

- (1) In the hospital's opinion, which has been agreed to by the intermediary, the services to be furnished are not considered reasonable and necessary under Medicare.
- (2) Customary charges will be made if he or she receives the services.
- (3) If the beneficiary receives the services, a formal determination on the validity of the hospital's finding is made by the intermediary and, to the extent that the decision requires the exercise of medical judgment, the PRO.
- (4) The determination is appealable by the hospital, the attending physician, or the beneficiary under the appeals procedure that applies to determinations affecting Medicare Part A payment.
- (5) The charges for the services will be invalid and, to the extent collected, will be refunded by the hospital if the services are found to be covered by Medicare.
- (e) Services furnished on days when the individual is not entitled to Medicare Part A benefits or has exhausted the available benefits. The hospital may charge the beneficiary its customary charges for noncovered items and services furnished on outlier days (as described in Subpart F of this part) for which payment is denied because the beneficiary is not entitled to Medicare Part A or his or her Medicare Part A benefits are exhausted. (1) If payment is considered for outlier days, the entire stay is reviewed and days up to the number of days in excess of the outlier threshold may be denied on the basis of nonentitlement to Part A or exhaustion of benefits. (2) In applying this rule, the latest days will be denied first.
- (f) Differential for private room or other luxury services. The hospital may

- charge the beneficiary the customary charge differential for a private room or other luxury service that is more expensive than is medically required and is furnished for the personal comfort of the beneficiary at his or her request (or the request of the person acting on his or her behalf).
- (g) Review. (1) The PRO or intermediary may review any cases in which the hospital advises the beneficiary (or the person acting on his or her behalf) of the noncoverage of the services in accordance with paragraph (c)(3) or (d) of this section.
- (2) The hospital must identify such cases to the PRO or intermediary in accordance with HCFA instructions.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 54 FR 41747, Oct. 11, 1989; 57 FR 39821, Sept. 1, 1992]

## §412.44 Medical review requirements: Admissions and quality review.

Beginning on November 15, 1984, a hospital must have an agreement with a PRO to have the PRO review, on an ongoing basis, the following:

- (a) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges.
- (b) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter.
- (c) The validity of the hospital's diagnostic and procedural information.
- (d) The completeness, adequacy, and quality of the services furnished in the hospital.
- (e) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

[50 FR 15326, Apr. 17, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 50 FR 41886, Oct. 16, 1985]

## §412.46 Medical review requirements: Physician acknowledgement.

(a) Basis. Because payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's